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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/687,911      | 10/13/2000  | Rostyslav Stoika     | CEDAR-44649         | 9562             |

7590 10/06/2003  
~~Edward G Poplawski Esq  
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EXAMINER

LI, QIAN J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/687,911

Applicant(s)

STOIKA ET AL.

Examiner

Q. Janice Li

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35, 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The amendment and response filed 7/18/2003 have been entered as Paper #14. Claims 35 and 53 have been amended, and are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims and argument (specifically, the correlation of mRNA and protein) will not be reiterated. The arguments in paper #14 would be addressed to the extent that they apply to current rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 53 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In paper #14, applicants argue that when T-cells are activated, they are proliferative, the two term describe the same state in T-cells, that when T cells respond to mitogen, the pttg mRNA level has changed, as such, the mitogen has activated the T

cell, whether the changes are immune-related or cell-cycle related, the distinction is merely semantic.

The argument has been fully considered but they are not persuasive for reasons of record and following.

As cited in the previous action, numerous prior art have indicated that the expression of PTTG is related to cell cycle progression, particularly proliferative state of a cell, as such, the PTTG expression is not T cell-specific. Accordingly, when the experimentation was conducted in T cells, the observed changes of PTTG mRNA level in T cells in response to various agents may not be immune-related but rather cell cycle-related. When a substance obtained by the claimed method is administered to a subject, it may affect wide variety of cells, rather than only regulating immune cells (immunosuppressive or immunoenhancing). Thus, even though T cell activation may be associated with its proliferation, the two conditions are not equal in terms of immunological function. The claims are drawn to screening substances for new immunosuppressive or immunoenhancing agents, thus, a nexus between the changes of PTTG mRNA and immune function of the T cells should be established to enable the claimed method, so that the substance obtained from practicing the method would be immune regulative rather than broadly acting on any cell with a proliferative state. To this end, the instant disclosure only established the cell cycle-related or proliferative changes in T cells in response to a mitogen, and fails to show that such changes have influenced the immunological function of T cells. Therefore, the specification fails to

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provide an enabling disclosure for obtaining a substance that specifically regulates immune response.

Applicants fail to respond to the following issues raised in the previous Office action (paper #13), which indicated that the specification fails to enable the claimed invention using any state and type of T lymphocytes (e.g. normal vs. tumor, and resting vs. activated). The following is the reiteration of the previous action.

Claims are drawn to a method using mammalian T lymphocytes, which T cells encompass normal T lymphocytes, resting and activated T lymphocytes, and T lymphocytes derived from lymphoma or leukemia. However, the specification teaches that hydrocortisone did not inhibit PTTG expression in Jurkat leukemia T cell line, and TGF- $\beta$ 1 did not affect PTTG expression in normal T cells (Specification, page 82, line 13-16, and page 83, lines 22-26). Further, claim 53 does not limit the state of T lymphocytes, however, apparently the resting state of the T lymphocytes would not reflect the changes of PTTG, and exposing T lymphocytes to a potential immunoenhancing agent may not change the proliferative state of the T cells unless the agent is a cell cycle regulator. In view of such, the claims do not appear to be enabled commensurate to the scope of the claims.

Accordingly, for reasons of record and those set forth foregoing, the specification fails to meet the statutory enablement requirement for the claimed invention.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
September 30, 2003

ANNE M. WEHBE' PH.D.  
PRIMARY EXAMINER

